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EXAMINER	
BEISNER, WILLIAM H	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

‹ 6

Office Action Summary	**Application No.** 10/678,059	**Applicant(s)** HORVATH, DOMONKOS	
	Examiner William H. Beisner	**Art Unit** 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2006 and 22 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-54* is/are pending in the application.

4a) Of the above claim(s) *51,53 and 54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-50 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/5/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 5/5/06 and 5/22/06 have been entered.

Election/Restrictions

2. Newly submitted claims 51, 53 and 54 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

In this case the combination as claimed in claims 35-50 and 52 does not employ the same membrane as recited in claim 51. For example the membrane of the combination of claims 35-50 and 52 requires a membrane that is "permeable for the exchange of nutrients at least for serum and structurally stable". The membrane of claim 51 does not require properties of serum exchange and/or that the membrane has to be structurally stable. Furthermore the membrane of claim 51 can be used in a culture device other than a device that includes means for moving the membrane. The invention of claims 35-50 and 52 is related to the invention of claims 53 and 54 as device and process for using the device. In this case, the invention of claims 35-50 and 52 are patentably distinct from the invention of claims 53 and 54 because the device of claims 35-50 and 52 can be used to perform a materially different process such as tissue culture other than for the regeneration of bone. For these reasons, the inventions of claims 35-50, 52; 51; and 53 and

53 are determined to be patentably distinct and are considered a "serious burden" to the Examiner, in view of the different classification of the claims and because a search for the invention of one group of claims would not encompass the same search required for the inventions of another group of claims, a burden would exist if the Examiner were required to examine all of the claims.

Information Disclosure Statement

3. The information disclosure statement filed 5/5/06 has been considered and made of record.

Claim Objections

4. Claim 35 is objected to because of the following informalities: As currently drafted, claim 35 makes reference to "claim 1 or 2"; however, these claims have been cancelled. Additionally note a proper dependent claim is required to include all of the limitations of the claim from which it depends. Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horvath et al.(WO 01/91663) in view of Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760).

The reference of Horvath et al. discloses a device for regeneration of tissue that includes a membrane (4) that is permeable for the exchange of nutrients and is structurally stable. The membrane has a surface that is to be bonded to a tissue (2) to be regenerated (See Figure 1). The device includes means or device (5,6) for moving membrane (4) with a certain pulling force and speed. Note the means or device (5,6) for moving the membrane is structurally the same as that instantly claimed and is capable of moving the membrane at a speed of 0.5 to 2 mm/day.

With respect to claim 35, the reference is silent as the use of a means for biological anchoring and adhesion for tissue or bone cells on the side of the membrane facing the tissue to be regenerated.

The references of Dee et al. and Meyer et al. both disclose that it is known in the art to provide the surfaces of implant devices with peptides for altering the cell adhesion properties of the implant material (See the abstracts of both references).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the membrane of the primary reference of Horvath et al. with peptides as suggested by the references of Dee et al. or Meyer et al. for the known and expected result of enhancing the adhesion of osteoblasts to the surface of the membrane which is required for the tissue regeneration process.

With respect to claims 36 and 37, the peptides suggested by the references of Dee et al. and Meyer et al. meet the claim limitations "protein molecules" or "short-chain molecules".

With respect to claim 38, it would have been obvious to provide the peptide coating over the entire surface of the membrane contacting the tissue to be regenerated.

With respect to claims 35, 39 and 40, osteoblasts would be anchored to the surface of the membrane since bone is being regenerated and the references of Dee et al. and Meyer et al. disclose that the peptide coating is for the adhesion of osteoblasts.

With respect to claim 41, the means for moving (5,6) the membrane (4) is a mechanical pulling means (See Figure 1).

4. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horvath et al.(WO 01/91663) in view of either Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760) taken further in view of Fromovich et al.(US 6,758,673).

The combination of the reference of Horvath et al. with either Dee et al. or Meyer et al. has been discussed above.

Claim 42 differs by reciting that the means for moving the membrane employs at least one magnet.

The reference of Fromovich et al. discloses that it is known in the art to gradually displace tissue when performing distraction osteogenesis using a variety of mechanical devices includes a magnetic device (See Figure 7).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a magnetic device for moving the membrane of the modified primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a device for gradual displacement of the membrane during the regeneration process.

5. Claims 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horvath et al.(WO 01/91663) in view of either Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760) taken further in view of Morgan (US 5,380,328).

The combination of the reference of Horvath et al. with either Dee et al. or Meyer et al. has been discussed above.

Claims 43-50 differ by reciting that the membrane includes a carrier.

The reference of Morgan discloses that it is known in the art to provide an implant membrane (16) with a carrier (14) that includes a plurality of passages.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the membrane of the primary reference with a carrier as disclosed by the reference of Morgan for the known and expected result of providing structural support for the membrane while providing the exchange and cell isolation associated with the membrane.

With respect to claim 44, the carrier is made of metal.

With respect to claim 45, the carrier is an open pore metal plate or grid or net.

With respect to claims 46-50, it would have been obvious to one of ordinary skill in the art to provide the previously discussed cell adhesion material on the carrier as well as the membrane for the known and expected result of enhancing the adhesion of osteoblasts to the surface of the membrane which is required for the tissue regeneration process.

6. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horvath et al.(WO 01/91663) in view of either Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760) taken further in view of Ledergerber (US 5,354,338).

The combination of the reference of Horvath et al. with either Dee et al. or Meyer et al. has been discussed above.

Claim 52 differs by reciting that the surface of the device is structured by sand blasting.

The reference of Ledergerber discloses that it is known in the art to microtexture the surface of an implant device using sand blasting so as to promote adhesion of the cells or tissue to the implant device (See the abstract and column 1, line 43, to column 2, line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to microtexture the surface of the device of the modified primary reference using sand blasting for the known and expected result of improving the adhesion of the implant to the tissue.

7. Claims 35-41 and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horvath et al.(WO 01/91663) in view of Robinson (US 5,839,899) and either Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760).

The reference of Horvath et al. discloses a device for regeneration of tissue that includes a membrane (4) that is permeable for the exchange of nutrients and is structurally stable. The membrane has a surface that is to be bonded to a tissue (2) to be regenerated (See Figure 1). The device includes means or device (5,6) for moving membrane (4) with a certain pulling force and speed. Note the means or device (5,6) for moving the membrane is structurally the same as that instantly claimed and is capable of moving the membrane at a speed of 0.5 to 2 mm/day.

If it is determined that the membrane (4) of the reference of Horvath et al. is not "permeable for the exchange of nutrients at least for serum and structurally stable", the reference of Robinson discloses that it is known in the art to employ permeable membranes for guided-tissue regeneration so as to promote the exchange of nutrients and blood supply between the graft and the overlying tissue (See column 4, lines 40-67).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a porous membrane for the known and expected result of providing nutrient exchange as is suggested by the reference of Robinson.

With respect to claim 35, the reference is silent as the use of a means for biological anchoring and adhesion for tissue or bone cells on the side of the membrane facing the tissue to be regenerated.

The references of Dee et al. and Meyer et al. both disclose that it is known in the art to provide the surfaces of implant devices with peptides for altering the cell adhesion properties of the implant material (See the abstracts of both references).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the membrane of the primary reference of Horvath et al. with peptides as suggested by the references of Dee et al. or Meyer et al. for the known and expected result of enhancing the adhesion of osteoblasts to the surface of the membrane which is required for the tissue regeneration process.

With respect to claims 36 and 37, the peptides suggested by the references of Dee et al. and Meyer et al. meet the claim limitations "protein molecules" or "short-chain molecules".

With respect to claim 38, it would have been obvious to provide the peptide coating over the entire surface of the membrane contacting the tissue to be regenerated.

With respect to claims 35, 39 and 40, osteoblasts would be anchored to the surface of the membrane since bone is being regenerated and the references of Dee et al. and Meyer et al. disclose that the peptide coating is for the adhesion of osteoblasts.

With respect to claim 41, the means for moving (5,6) the membrane (4) is a mechanical pulling means (See Figure 1).

With respect to claims 43-45, the reference of Robinson discloses the use of a carrier is made of metal and is made of an open pore metal plate or grid or net.

With respect to claims 46-50, it would have been obvious to one of ordinary skill in the art to provide the previously discussed cell adhesion material on the carrier as well as the membrane for the known and expected result of enhancing the adhesion of osteoblasts to the surface of the membrane which is required for the tissue regeneration process.

8. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horvath et al.(WO 01/91663) in view of Robinson (US 5,839,899) and either Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760) taken further in view of Fromovich et al.(US 6,758,673).

The combination of the reference of Horvath et al. and Robinson with either Dee et al. or Meyer et al. has been discussed above.

Claim 42 differs by reciting that the means for moving the membrane employs at least one magnet.

The reference of Fromovich et al. discloses that it is known in the art to gradually displace tissue when performing distraction osteogenesis using a variety of mechanical devices includes a magnetic device (See Figure 7).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a magnetic device for moving the membrane of the modified primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result, providing a device for gradual displacement of the membrane during the regeneration process.

9. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horvath et al.(WO 01/91663) in view of Robinson (US 5,839,899) and either Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760) taken further in view of Ledergerber (US 5,354,338).

The combination of the reference of Horvath et al. and Robinson with either Dee et al. or Meyer et al. has been discussed above.

Claim 52 differs by reciting that the surface of the device is structured by sand blasting.

The reference of Ledergerber discloses that it is known in the art to microtexture the surface of an implant device using sand blasting so as to promote adhesion of the cells or tissue to the implant device (See the abstract and column 1, line 43, to column 2, line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to microtexture the surface of the device of the modified primary reference using sand blasting for the known and expected result of improving the adhesion of the implant to the tissue.

10. Claims 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gogolewski et al.(US 5,676,699) in view of Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760).

The reference of Gogolewski et al. discloses a device for regeneration of tissue that includes a membrane (1) that is permeable for the exchange of nutrients and is structurally stable. The membrane has a surface that is to be bonded to a tissue (inner surface of the cylindrical membrane) to be regenerated (See Figures 2-4). The device includes means or device (9) that is capable of moving the membrane (1) with a certain pulling force and speed. Note the means or device (9) for moving the membrane is structurally the same as that instantly claimed and is capable of moving the membrane at a speed of 0.5 to 2 mm/day.

With respect to claim 35, the reference is silent as the use of a means for biological anchoring and adhesion for tissue or bone cells on the side of the membrane facing the tissue to be regenerated.

The references of Dee et al. and Meyer et al. both disclose that it is known in the art to provide the surfaces of implant devices with peptides for altering the cell adhesion properties of the implant material (See the abstracts of both references).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the membrane of the primary reference of Horvath et al. with peptides as suggested by the references of Dee et al. or Meyer et al. for the known and expected result of enhancing the adhesion of osteoblasts to the surface of the membrane which is required for the tissue regeneration process.

With respect to claims 36 and 37, the peptides suggested by the references of Dee et al. and Meyer et al. meet the claim limitations “protein molecules” or “short-chain molecules”.

With respect to claim 38, it would have been obvious to provide the peptide coating over the entire surface of the membrane contacting the tissue to be regenerated.

With respect to claims 35, 39 and 40, osteoblasts would be anchored to the surface of the membrane since bone is being regenerated and the references of Dee et al. and Meyer et al. disclose that the peptide coating is for the adhesion of osteoblasts.

With respect to claim 40, the means for moving (9) the membrane (1) is a mechanical pulling means (See Figure 2).

11. Claims 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gogolewski et al.(US 5,676,699) in view of Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760) taken further in view of Morgan (US 5,380,328).

The combination of the reference Gogolewski with either Dee et al. or Meyer et al. has been discussed above.

Claims 43-50 differ by reciting that the membrane includes a carrier.

The reference of Morgan discloses that it is known in the art to provide an implant membrane (16) with a carrier (14) that includes a plurality of passages.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the membrane of the primary reference with a carrier as disclosed by the reference of

Morgan for the known and expected result of providing structural support for the membrane while providing the exchange and cell isolation associated with the membrane.

With respect to claim 44, the carrier is made of metal.

With respect to claim 45, the carrier is an open pore metal plate or grid or net.

With respect to claims 46-50, it would have been obvious to one of ordinary skill in the art to provide the previously discussed cell adhesion material on the carrier as well as the membrane for the known and expected result of enhancing the adhesion of osteoblasts to the surface of the membrane which is required for the tissue regeneration process.

12. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gogolewski et al.(US 5,676,699) in view of Dee et al.(WO 97/25999) or Meyer et al.(US 6,280,760) taken further in view of Ledergerber (US 5,354,338).

The combination of the reference Gogolewski with either Dee et al. or Meyer et al. has been discussed above.

Claim 52 differs by reciting that the surface of the device is structured by sand blasting.

The reference of Ledergerber discloses that it is known in the art to microtexture the surface of an implant device using sand blasting so as to promote adhesion of the cells or tissue to the implant device (See the abstract and column 1, line 43, to column 2, line 24).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to microtexture the surface of the device of the modified primary reference using sand blasting for the known and expected result of improving the adhesion of the implant to the tissue.

Response to Arguments

13. With respect to the rejection of claims 30-33 over the combination of the references of Horvath with Dee or Meyer; or Horvath with Robinson and Dee or Meyer; or Gogolewski with Dee or Meyer, Applicant argues that new claim 35 would not be obvious in view of these references because new claim 35 requires that the membrane includes "a pulling speed of 0.5-2 mm/day". Applicant stresses that the implants of the references of Dee, Meyer, Robinson and Gogolewski are not moved when implanted and that one of ordinary skill in the art would not have attached the osteoblasts to a membrane of Horvath when desiring to move the membrane with a speed of 0.5-2 mm/day because this would be detrimental to the osteoblasts in view of the prior art evidence submitted by applicants.

Applicant's arguments are not found to be persuasive for the following reasons:

i) The instant claim is a device claim and statements of intended use carry no patentable weigh in apparatus-type claims. The moving device of Horvath is capable of providing the required movement of claim 35.

ii) While instant claim 35 recites that osteoblasts are incorporated on the device, the Examiner is of the position that when using the device, osteoblasts will be incorporated in the device since the device is used for bone regeneration. The fact that applicant intends that osteoblasts are provided on the device prior to use is immaterial since the instant claim is a device claim rather than a method claim.

iii) While one of ordinary skill in the art may not be motivated to provide the device of Horvath with osteoblasts as argued, the prior art of record suggests providing implant devices with cell adhesion material. Use of the device of Horvath intends and requires cell adhesion to the device during the implantation process. As a result, one of ordinary skill in the art would clearly be motivated to provide the device of Horvath with cell adhesion properties regardless if the membrane of the device is fixed and/or moved.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

William H. Beisner
Primary Examiner
Art Unit 1744

WHB